UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

BARBARA HEINRICH and GREGORY HEINRICH,

Plaintiffs

v.

ETHICON, INC.; ETHICON LLC; and JOHNSON & JOHNSON,

Defendants

Case No.: 2:20-cv-00166-APG-VCF

Order Granting in Part Defendants' Motion in Limine No. 7

[ECF No. 135]

This case is one of many thousands of cases that were joined in multidistrict litigation (MDL) in the United States District Court for the Southern District of West Virginia. The case was transferred to this court for trial in January 2020. ECF No. 69.

The defendants filed a motion *in limine* seeking to exclude from trial evidence about "foreign regulations, websites, labels, or any other document generated only pursuant to foreign regulatory requirements." ECF No. 135 at 2. The defendants also identify five specific categories of information they seek to exclude: (1) a "quality block" placed on TVT-S shipments in Australia, (2) Ethicon's investigations in Australia and Germany, (3) the resulting root cause analysis, Quality Boards, updates to Professional Education, communications with the Therapeutic Goods Administration (TGA), which is an Australian regulatory body, retraining efforts, and communications regarding potential remedial actions; (4) communications related to German doctors' experiences with the TVT-S, and (5) documents discussing other countries where Ethicon stopped marketing TVT-S. ECF No. 135 at 2.

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A. Foreign Regulations and Communications with Foreign Regulatory Bodies

The defendants contend the plaintiffs should not be allowed to present evidence about foreign regulations or their communications with foreign regulatory bodies. The plaintiffs respond that they do not intend to present evidence about foreign regulations. The plaintiffs do not address the defendants' argument that their communications with foreign regulatory bodies should also be excluded. I grant this portion of the defendants' motion as unopposed. LR 7-2(d). Evidence of foreign regulations, the defendants' communications with foreign regulatory bodies, or any orders issued by foreign regulatory bodies is excluded.

B. Evidence of Australian and German Doctors' Experiences/Complaints

The defendants seek to exclude evidence that some Australian and German physicians experienced failures with the TVT-S, meaning the device did not cure the patients' stress urinary incontinence. They also seek to exclude the defendants' response to these complaints, including internal investigations and a quality block placed on the TVT-S in Australia by Dr. Aran Maree, who was the medical director at Johnson & Johnson Australia/New Zealand. The defendants argue that problems experienced by a handful of doctors in Australia and Germany are not relevant to Barbara Heinrich's implantation in the United States. They also contend the evidence is unfairly prejudicial. And they assert that subsequent remedial measures are not admissible under Federal Rule of Evidence 407.

The plaintiffs respond that the experiences of the doctors in Germany and Australia were not isolated instances, as shown by doctors in the United States and elsewhere around the world who also had high failure rates early on in their experiences with the TVT-S. The plaintiffs contend this evidence is probative of the defendants' knowledge that the TVT-S's instructions for use were defective because doctors did not know how to implant it, were given inadequate

instructions on how to do so, and were putting women into retention. The plaintiffs contend that despite being on notice, the defendants did not advise Barbara Heinrich's implanting physician of these problems before her surgery. The plaintiffs note that Barbara Heinrich's implanting physician testified that if he had known about the complaints by the German and Australian doctors, he may have chosen a different treatment option for her.

Evidence of physicians reporting to the defendants that they were experiencing high failure rates using the TVT-S and the defendants' internal response[1] to those complaints is relevant to the plaintiffs' claims that the device and its instructions for use were defective, and that defendants knew but failed to warn Barbara Heinrich's implanting physician. Although the defendants contend the problems were isolated and not replicated in the United States, the plaintiffs have pointed to evidence that physicians in the United States experienced similar problems. *See, e.g.*, ECF Nos. 155-3 at 5 (internal Ethicon email stating that "much relearning had to occur to gain success in the US and particularly Europe" with the TVT-S); 155-6 at 4 (internal Ethicon email discussing US preceptors' issues with TVT-S, including "[w]hat (and why) is the right tension").

The risk of unfair prejudice does not substantially outweigh this evidence's probative value. The defendants will be able to explain to the jury their position that the problems were not the result of the device or its instructions for use, but rather the implantation techniques of a handful of surgeons. It is for the jury to resolve whether the results were due to poor physician practices as opposed to problems with the device and its accompanying instructions.

[1] There is no evidence before me that any quality reviews, "root cause" analyses, quality boards, or quality blocks were ordered by a foreign regulatory body.

Finally, although the defendants argue evidence of subsequent remedial measures is inadmissible under Federal Rule of Evidence 407, the evidence the defendants attach to their motion predates Barbara Heinrich's March 2008 implantation. Any remedial measure the defendants took in response to the physicians' complaints but before Barbara Heinrich's implantation would not fall under Rule 407 because those actions would not be subsequent remedial measures that would have made Barbara Heinrich's injuries less likely to occur.

C. Marketing Ceased in Other Countries

The defendants seek to exclude as unfairly prejudicial evidence that Ethicon ceased marketing TVT-S in other countries. The plaintiffs do not address this portion of the defendants' motion. I therefore grant it as unopposed. LR 7-2(d).

D. Conclusion

I THEREFORE ORDER that the defendants' motion *in limine* No. 7 **(ECF No. 135) is GRANTED in part** as discussed above.

DATED this 1st day of November, 2021.

ANDREW P. GORDON
UNITED STATES DISTRICT JUDGE